

## REMARKS

Claims 41-44, 52, 55 and 56 were examined in the Office Action under reply. Applicants note with appreciation the withdrawal of the previous rejections under the judicially created doctrine of obviousness-type double patenting, as well as the withdrawal of the previous rejection under 35 U.S.C. §112, second paragraph.

All claims now stand rejected under the judicially created doctrine of obviousness-type double patenting as follows:

(1) Claims 41-44 and 52 stand rejected over claims 8, 24, 33 and 38 of U.S. Patent No. 6,630,298 (USSN 09/881,239);

(2) Claims 41-44 and 52 stand rejected over claims 5-8 and 11-21 of U.S. Patent No. 6,632,601 (USSN 09/881,654);

(3) Claims 41-44, 52, 55 and 56 stand rejected over claims 1-4 of U.S. Patent No. 6,797,809;

(4) Claims 41-44, 52, 55 and 56 stand rejected over claims 8, 12, 31 and 44-58 of USSN 10/643,853 (DIV of 09/881,239);

(5) Claims 41-44, 52, 55 and 56 stand rejected over claims 6-14, 16, 17, 19, 20 and 22-47 of USSN 10/899,715 (CON of 09/881,654); and

(6) Claims 41-44 and 52 stand rejected over claims 15, 16, 31 and 32 of USSN 10/658,782.

Applicants are submitting a terminal disclaimer over the '809 patent (rejection number (3) above). However, the rejections over the remaining patents and patent applications are respectfully traversed.

The claims pending in the present application are directed to fusion proteins and immunogenic compositions comprising the proteins. None of the claims in the patents and applications from rejections (1), (2), (4), (5) and (6) above pertain to fusion proteins. In particular, claims 8, 24, 33 and 38 of the '298 patent (rejection number (1) above) relate to immunoassay solid supports (claims 8 and 33); an immunoassay method (claim 24); and an immunodiagnostic test kit (claim 38). Applicants submit that fusion proteins are separately patentable and that a terminal disclaimer is not necessary. In fact, the Patent Office appears to agree with this view. More specifically, there was a three-way restriction requirement (dated

June 11, 2002) in the '298 patent that named three groups of claims -- Group I, claims 1-43, drawn to a solid support with bound antigens, kit, method of use in immunoassays and method of making; Group II, claims 44-46, drawn to a fusion antigen; and Group III, claims 47-58, drawn to a polynucleotide, vector, host cell and method of making a protein. Thus, the Patent Office itself recognizes that fusion proteins are separate and distinct from immunoassay solid supports, immunoassay methods and immunodiagnostic test kits. Since fusion proteins constitute a separately patentable invention, applicants respectfully request withdrawal of the obviousness-type double patenting rejection over the '298 patent.

Rejection (2) above, over U.S. Patent No. 6,632,601 is also respectfully traversed. As with the '298 patent discussed above, claims 5-8 and 11-21 relate to immunoassay solid supports (claims 5-8, 11-14 and 17); immunoassay methods (claims 15 and 19); immunodiagnostic test kits (claims 16 and 18); and methods of producing an immunoassay solid support (claims 20 and 21). The Patent Office issued a three-way restriction requirement dated June 11, 2002 in the '601 patent as follows: Group I, claims 1-24, drawn to a solid support, kit, methods of use and methods of making; Group II, claims 25-28, drawn to a fusion antigen; and Group III, claims 29-47, drawn to a polynucleotide, vector, host cell and methods of recombinant production. Accordingly, as with the obviousness-type double patenting rejection discussed above, the present rejection is inappropriate as claims 1-24 were considered to be separately patentable from fusion antigens. Withdrawal of the rejection over the '601 patent is therefore respectfully requested.

Rejection (4) is also believed to be improper. In particular, the Office rejected the present claims over claims 8, 12, 31 and 44-58 of USSN 10/643,853. Applicants note that only claims 47-58 are currently pending in the '853 application. The pending claims relate to polynucleotides (claims 47-49); recombinant vectors (claims 50-52); host cells (claims 53-55) and methods of recombinant production (claims 56-58). In fact, the '853 application is a divisional of U.S. Patent No. 6,630,298 (USSN 09/881,239), discussed above. This divisional was filed because the polynucleotide, vector, host cell and recombinant production claims in the '298 patent were restricted from the fusion protein claims. See, above. Thus, requiring a Terminal Disclaimer over claims pertaining to polynucleotides is inappropriate and withdrawal of this basis for rejection is respectfully requested.

As with rejection (4) discussed above, rejection (5) is also improper. The Office rejected the claims over claims 6-14, 16, 17, 19, 20 and 22-47 of USSN 10/899,715. Claims 29-47 are currently pending in the '715 application. The pending claims of the '715 application relate to polynucleotides (claims 29-35); recombinant vectors (claims 36-39); host cells (claims 40-43) and methods of recombinant production (claims 44-47). The '715 application is a continuation of U.S. Patent No. 6,632,601 (USSN 09/881,654), discussed above. As explained above, the polynucleotide, vector, host cell and recombinant production claims in the '601 patent were restricted from the fusion protein claims. Thus, requiring a Terminal Disclaimer over the '601 patent is improper and withdrawal of this basis for rejection is respectfully requested.

Finally, rejection (6) is believed to be inappropriate. Claims 41-44 and 52 stand rejected over claims 15, 16, 31 and 32 of USSN 10/658,782. Claims 15, 16, 31 and 32 of the '782 application all pertain to immunoassay methods. The Patent Office, in an Office Action dated January 26, 2005, determined that claims to fusion antigens were independent and distinct from the immunoassay method claims. Thus, a Terminal Disclaimer over the '782 application is also not necessary and withdrawal of this basis for rejection is respectfully requested.

### CONCLUSION

Applicants respectfully submit that the claims are now in condition for allowance. Accordingly, an early notification to that effect would be appreciated.

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Respectfully submitted,

Dated: 9/29/05

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